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GENERAL ELECTRIC COMPANY and GE
HEALTHCARE INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

PETER JAY GERBER and MIRIAM
GOLDBERG,

Plaintiffs,

v.

BAYER CORPORATION AND
BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BMC
DIAGNOSTICS, INC.; CALIFORNIA
PACIFIC MEDICAL CENTER;
GENERAL ELECTRIC COMPANY;
GE HEALTHCARE, INC.; GE
HEALTHCARE BIO-SCIENCES
CORP.; McKESSON
CORPORATION; MERRY X-RAY
CHEMICAL CORP.; and DOES 1
through 35

Defendants.

CASE NO. CV-07-5918-EDL

**GENERAL ELECTRIC COMPANY AND
GE HEALTHCARE INC.'S ANSWER TO
COMPLAINT**

[Jury Trial Demanded]

(San Francisco County Superior Court Case No.
CGC07468577)

COME NOW Defendants GENERAL ELECTRIC COMPANY and GE
HEALTHCARE INC. (incorrectly sued as GE Healthcare, Inc.) (collectively,
“Defendants”) and respond to the Plaintiff’s Complaint as follows:

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1 1. Defendants admit that nephrogenic systemic fibrosis (“NSF”) is a rare,
2 acquired systemic disease, which may lead to the increased formation of connective tissue
3 in the skin, causing it to become thickened, coarse, and hard, leading to disabling
4 contractures. NSF is progressive and may be fatal. Defendants expressly deny Paragraph
5 1 to the extent it purports to expand, or alter the meaning of, or is otherwise inconsistent
6 with, the accepted medical and scientific definition of NSF, also known as nephrogenic
7 fibrosing dermopathy. Defendants are without knowledge or information sufficient to
8 form a belief as to the truth of the remaining allegations contained in Paragraph 1 and
9 therefore deny the same.

10 2. Paragraph 2 is directed to another defendant and thus requires no response.
11 In the alternative, Defendants are without knowledge or information sufficient to form a
12 belief as to the truth of the allegations contained in Paragraph 2 and therefore deny the
13 same.

14 3. Paragraph 3 is directed to another defendant and thus requires no response.
15 In the alternative, Defendants are without knowledge or information sufficient to form a
16 belief as to the truth of the allegations contained in Paragraph 3 and therefore deny the
17 same.

18 4. Paragraph 4 is directed to another defendant and thus requires no response.
19 In the alternative, Defendants are without knowledge or information sufficient to form a
20 belief as to the truth of the allegations contained in Paragraph 4 and therefore deny the
21 same.

22 5. Paragraph 5 is directed to another defendant and thus requires no response.
23 In the alternative, Defendants are without knowledge or information sufficient to form a
24 belief as to the truth of the allegations contained in Paragraph 5 and therefore deny the
25 same.

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1 6. Paragraph 6 is directed to another defendant and thus requires no response.
2 In the alternative, Defendants are without knowledge or information sufficient to form a
3 belief as to the truth of the allegations contained in Paragraph 6 and therefore deny the
4 same.

5 7. Paragraph 7 is directed to another defendant and thus requires no response.
6 In the alternative, Defendants are without knowledge or information sufficient to form a
7 belief as to the truth of the allegations contained in Paragraph 7 and therefore deny the
8 same.

9 8. Defendants admit that Omniscan™ is a gadolinium-based contrast agent that
10 is FDA approved for use in the United States in MRI procedures. Defendants deny that
11 GE Healthcare Bio-Sciences is engaged in any commercial or other activity with respect
12 to Omniscan™, or any other diagnostic medical imaging contrast agents. Defendants
13 admit that GE Healthcare Inc. distributes, sells and supplies Omniscan™ in the United
14 States in accordance with FDA rules and regulations. Defendants further admit that
15 General Electric Company, as the ultimate parent company, indirectly manufactures,
16 distributes, sells and markets Omniscan™ in the United States in accordance with FDA
17 rules and regulations. Defendant General Electric Company further admits that the MR
18 sub-unit of its Diagnostic Imaging Unit manufactures MR machines. Defendants are
19 without knowledge or information sufficient to form a belief as to the truth of the
20 allegations contained in Paragraph 8 and therefore deny the same.

21 9. Defendants admit that General Electric Company is a New York company
22 with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut,
23 06828. Except as admitted, Defendants deny the allegations contained in Paragraph 9.

24 10. Defendants admit that General Electric Company conducts business in the
25 State of California. Except as admitted, the Defendants deny the allegations contained in
26 Paragraph 10.

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1 11. Defendants admit that GE Healthcare Inc. is a Delaware corporation, with
2 its principal place of business at 101 Carnegie Center, Princeton, New Jersey, 08540.
3 Except as admitted, Defendants deny the allegations contained in Paragraph 11.

4 12. Defendants admit that GE Healthcare Inc. conducts business in the State of
5 California. Except as admitted, the Defendants deny the allegations contained in
6 Paragraph 12.

7 13. Defendants admit that GE Healthcare Bio-Sciences Corp. is a Delaware
8 corporation, with its principal place of business at 800 Centennial Avenue, Piscataway,
9 New Jersey, 08855. Except as admitted, the Defendants deny the allegations contained in
10 Paragraph 13.

11 14. Defendants admit that GE Healthcare Bio-Sciences Corp. conducts business
12 in the State of California. Defendants deny that GE Healthcare Bio-Sciences is engaged
13 in any commercial or other activity with respect to Omniscan™, or any other diagnostic
14 medical imaging contrast agents. Except as admitted, the Defendants deny the allegations
15 contained in Paragraph 14.

16 15. Defendants admit that GE Healthcare Inc. sells Omniscan™ in the State of
17 California. Defendants further admit that General Electric Company sells MR machines
18 in the State of California. Except as admitted, the Defendants deny the allegations
19 contained in Paragraph 15.

20 16. Defendants are without knowledge or information sufficient to form a belief
21 as to the truth of the allegations contained in Paragraph 16 and therefore deny the same.

22 17. Defendants are without knowledge or information sufficient to form a belief
23 as to the truth of the allegations contained in Paragraph 17 and therefore deny the same.

24 18. Defendants are without knowledge or information sufficient to form a belief
25 as to the truth of the allegations contained in Paragraph 18 and therefore deny the same.

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1 19. Paragraph 19 does not require a response. To the extent Paragraph 19 is
2 deemed to require a response, Defendants are without knowledge or information sufficient
3 to form a belief as to the truth of the allegations contained in Paragraph 19 and therefore
4 deny the same.

5 20. Paragraph 20 is directed to another defendant and thus requires no response.
6 In the alternative, Defendants are without knowledge or information sufficient to form a
7 belief as to the truth of the allegations contained in Paragraph 20 and therefore deny the
8 same.

9 21. Paragraph 21 is directed to another defendant and thus requires no response.
10 In the alternative, Defendants are without knowledge or information sufficient to form a
11 belief as to the truth of the allegations contained in Paragraph 21 and therefore deny the
12 same.

13 22. Paragraph 22 is directed to another defendant and thus requires no response.
14 In the alternative, Defendants are without knowledge or information sufficient to form a
15 belief as to the truth of the allegations contained in Paragraph 22 and therefore deny the
16 same.

17 23. Paragraph 23 is directed to another defendant and thus requires no response.
18 In the alternative, Defendants are without knowledge or information sufficient to form a
19 belief as to the truth of the allegations contained in Paragraph 23 and therefore deny the
20 same.

21 24. Paragraph 24 is directed to another defendant and thus requires no response.
22 In the alternative, Defendants are without knowledge or information sufficient to form a
23 belief as to the truth of the allegations contained in Paragraph 24 and therefore deny the
24 same.

25 25. Paragraph 25 is directed to another defendant and thus requires no response.
26 In the alternative, Defendants are without knowledge or information sufficient to form a
27 belief as to the truth of the allegations contained in Paragraph 25 and therefore deny the
28 same.

1 26. Paragraph 26 is directed to another defendant and thus requires no response.
2 In the alternative, Defendants are without knowledge or information sufficient to form a
3 belief as to the truth of the allegations contained in Paragraph 26 and therefore deny the
4 same.

5 27. Paragraph 27 is directed to another defendant and thus requires no response.
6 In the alternative, Defendants are without knowledge or information sufficient to form a
7 belief as to the truth of the allegations contained in Paragraph 27 and therefore deny the
8 same.

9 28. Defendants are without knowledge or information sufficient to form a belief
10 as to the truth of the allegations contained in Paragraph 28 and therefore deny the same.

11 29. Defendants are without knowledge or information sufficient to form a belief
12 as to the truth of the allegations contained in Paragraph 29 and therefore deny the same.

13 30. Defendants are without knowledge or information sufficient to form a belief
14 as to the truth of the allegations contained in Paragraph 30 and therefore deny the same.

15 31. Paragraph 31 does not require a response. To the extent Paragraph 31 is deemed to
16 require a response, Defendants are without knowledge or information sufficient to form a
17 belief as to the truth of the allegations contained in Paragraph 31 and therefore deny the
18 same.

19 32. Defendants are without knowledge or information sufficient to form a belief
20 as to the truth of the allegations contained in Paragraph 32 and therefore deny the same.

21 33. Paragraph 33 is directed to another defendant and thus requires no response.
22 In the alternative, Defendants are without knowledge or information sufficient to form a
23 belief as to the truth of the allegations contained in Paragraph 33 and therefore deny the
24 same.

25 34. Paragraph 34 is directed to another defendant and thus requires no response.
26 In the alternative, Defendants are without knowledge or information sufficient to form a
27 belief as to the truth of the allegations contained in Paragraph 34 and therefore deny the
28 same

1 35. Defendants are without knowledge or information sufficient to form a belief
2 as to the truth of the allegations contained in Paragraph 35 and therefore deny the same.

3 36. Paragraph 36 is directed to another defendant and thus requires no response.
4 In the alternative, Defendants are without knowledge or information sufficient to form a
5 belief as to the truth of the allegations contained in Paragraph 36 and therefore deny the
6 same.

7 37. Paragraph 37 is directed to another defendant and thus requires no response.
8 In the alternative, Defendants are without knowledge or information sufficient to form a
9 belief as to the truth of the allegations contained in Paragraph 37 and therefore deny the
10 same.

11 38. Defendants are without knowledge or information sufficient to form a belief
12 as to the truth of the allegations contained in Paragraph 38 and therefore deny the same.

13 39. Defendants are without knowledge or information sufficient to form a belief
14 as to the truth of the allegations contained in Paragraph 39 and therefore deny the same.

15 40. Defendants are without knowledge or information sufficient to form a belief
16 as to the truth of the allegations contained in Paragraph 40 and therefore deny the same.

17 41. Paragraph 41 does not require a response. To the extent Paragraph 41 is
18 deemed to require a response, Defendants are without knowledge or information sufficient
19 to form a belief as to the truth of the allegations contained in Paragraph 41 and therefore
20 deny the same.

21 42. Paragraph 42 does not require a response. To the extent Paragraph 42 is
22 deemed to require a response, Defendants are without knowledge or information sufficient
23 to form a belief as to the truth of the allegations contained in Paragraph 42 and therefore
24 deny the same.

25 43. Defendants admit that NSF is a rare, acquired systemic disease, which is
26 progressive and may be fatal. Defendants expressly deny Paragraph 43 to the extent it
27 purports to expand, or alter the meaning of, or is otherwise inconsistent with, the accepted
28 medical and scientific definition of nephrogenic systemic fibrosis, also known as

1 nephrogenic fibrosing dermopathy. Defendants are without knowledge or information
2 sufficient to form a belief as to the truth of the allegations contained in Paragraph 43 and
3 therefore deny the same.

4 44. Defendants admit that NSF is rare, acquired systemic disease, which may
5 lead to the increased formation of connective tissue in the skin, causing it to become
6 thickened, coarse, and hard, leading to disabling contractures. NSF is progressive and
7 may be fatal. Defendants admit that NSF was first reported in medical literature in 2000,
8 referencing a case from 1997. Defendants expressly deny Paragraph 44 to the extent it
9 purports to expand, or alter the meaning of, or is otherwise inconsistent with, the accepted
10 medical and scientific definition of nephrogenic systemic fibrosis, also known as
11 nephrogenic fibrosing dermopathy. Except as admitted, Defendants deny the allegations
12 contained in Paragraph 44.

13 45. Defendants deny the allegations contained in Paragraph 45.

14 46. Paragraph 46 contains scientific conclusions to which no response is
15 required. To the extent that a response is deemed to be required, Defendants expressly
16 deny Paragraph 46 to the extent it purports to expand, or alter the meaning of, or is
17 otherwise inconsistent with, the accepted scientific definition of gadolinium. Except as
18 admitted, Defendants deny the allegations contained in Paragraph 46.

19 47. Paragraph 47 contains scientific conclusions to which no response is
20 required. To the extent that a response is deemed to be required, Defendants expressly
21 deny Paragraph 46 to the extent it purports to expand, or alter the meaning of, or is
22 otherwise inconsistent with, the accepted scientific definition of gadolinium or chelation.
23 Except as admitted, Defendants deny the allegations contained in Paragraph 47.

24 48. Defendants admit that Omniscan™ is cleared from the body through the
25 kidneys by glomerular filtration. Except as admitted, Defendants deny the allegations
26 contained in Paragraph 48.

27 49. Defendants admit that Omniscan™ is a gadolinium-based contrast agent that
28 is FDA approved for use in the United States in MRI procedures. Defendants further

1 admit that the FDA has not approved any gadolinium-based contrast agents for use in
2 MRA in the United States. Defendants are without knowledge or information sufficient to
3 form a belief as to the truth of the remaining allegations contained in Paragraph 49 and
4 therefore deny the same.

5 50. Defendants deny the allegations contained in Paragraph 50.

6 51. Defendants admit that the ligand utilized in Omniscan™ has a linear
7 structure. Except as admitted, Defendants deny the allegations contained in Paragraph 51.

8 52. Defendants admit that the Omniscan™ label has contained warnings
9 regarding impaired kidney function since the product was placed on the market in 1993.
10 Defendants are without knowledge or information sufficient to form a belief as to the truth
11 of the remaining allegations contained in Paragraph 52 and therefore deny the same.

12 53. Defendants deny the allegations contained in Paragraph 53.

13 54. Defendants are without knowledge or information sufficient to form a belief
14 as to the truth of the allegations contained in Paragraph 54 and therefore deny the same.

15 55. Defendants are without knowledge or information sufficient to form a belief
16 as to the truth of the allegations contained in Paragraph 55 and therefore deny the same.

17 56. Defendants deny the allegations contained in Paragraph 56.

18 57. Defendants deny the allegations contained in Paragraph 57.

19 58. Defendants deny the allegations contained in Paragraph 58.

20 59. Defendants deny the allegations contained in Paragraph 59.

21 60. Defendants are without knowledge or information sufficient to form a belief
22 as to the truth of the allegations contained in Paragraph 60 and therefore deny the same.

23 61. Defendants deny the allegations contained in Paragraph 61.

24 62. Defendants deny the allegations contained in Paragraph 62.

25 63. Defendants deny the allegations contained in Paragraph 63.

26 64. Defendants deny the allegations contained in Paragraph 64.

27 65. Defendants deny the allegations contained in Paragraph 65.

28 66. Defendants deny the allegations contained in Paragraph 66.

1 67. Defendants deny the allegations contained in Paragraph 67.

2 68. Defendants deny the allegations contained in Paragraph 68.

3 69. Defendants hereby incorporate their responses to the allegations contained
4 in Paragraphs 1 through 68 as if set forth fully herein.

5 70. Defendants deny the allegations contained in Paragraph 70.

6 71. Defendants deny the allegations contained in Paragraph 71.

7 72. Defendants hereby incorporate their responses to the allegations contained
8 in Paragraphs 1 through 71 as if set forth fully herein.

9 73. Paragraph 73 contains a legal conclusion to which no response is required.
10 To the extent that a response is deemed to be required, Defendants deny the allegations
11 contained in Paragraph 73.

12 74. Defendants deny the allegations contained in Paragraph 74.

13 75. Defendants deny the allegations contained in Paragraph 75.

14 76. Defendants deny the allegations contained in Paragraph 76.

15 77. Defendants deny the allegations contained in Paragraph 77.

16 78. Defendants deny the allegations contained in Paragraph 78.

17 79. Defendants deny the allegations contained in Paragraph 79.

18 80. Defendants hereby incorporate their responses to the allegations contained
19 in Paragraphs 1 through 79 as if set forth fully herein.

20 81. Paragraph 81 is directed to another defendant and thus requires no response.
21 In the alternative, Defendants are without knowledge or information sufficient to form a
22 belief as to the truth of the allegations contained in Paragraph 81 and therefore deny the
23 same.

24 82. Paragraph 82 is directed to another defendant and thus requires no response.
25 In the alternative, Defendants are without knowledge or information sufficient to form a
26 belief as to the truth of the allegations contained in Paragraph 82 and therefore deny the
27 same.

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1 83. Paragraph 83 is directed to another defendant and thus requires no response.
2 In the alternative, Defendants are without knowledge or information sufficient to form a
3 belief as to the truth of the allegations contained in Paragraph 83 and therefore deny the
4 same.

5 84. Paragraph 84 is directed to another defendant and thus requires no response.
6 In the alternative, Defendants are without knowledge or information sufficient to form a
7 belief as to the truth of the allegations contained in Paragraph 84 and therefore deny the
8 same.

9 85. Paragraph 85 is directed to another defendant and thus requires no response.
10 In the alternative, Defendants are without knowledge or information sufficient to form a
11 belief as to the truth of the allegations contained in Paragraph 85 and therefore deny the
12 same.

13 86. Paragraph 86 is directed to another defendant and thus requires no response.
14 In the alternative, Defendants are without knowledge or information sufficient to form a
15 belief as to the truth of the allegations contained in Paragraph 86 and therefore deny the
16 same.

17 87. Paragraph 87 is directed to another defendant and thus requires no response.
18 In the alternative, Defendants are without knowledge or information sufficient to form a
19 belief as to the truth of the allegations contained in Paragraph 87 and therefore deny the
20 same.

21 88. Paragraph 88 is directed to another defendant and thus requires no response.
22 In the alternative, Defendants are without knowledge or information sufficient to form a
23 belief as to the truth of the allegations contained in Paragraph 88 and therefore deny the
24 same.

25 89. Defendants hereby incorporate their responses to the allegations contained
26 in Paragraphs 1 through 88 as if set forth fully herein.

27 90. Paragraph 90 is directed to another defendant and thus requires no response.
28 In the alternative, Defendants are without knowledge or information sufficient to form a

1 belief as to the truth of the allegations contained in Paragraph 90 and therefore deny the
2 same.

3 91. Paragraph 91 is directed to another defendant and thus requires no response.
4 In the alternative, Defendants are without knowledge or information sufficient to form a
5 belief as to the truth of the allegations contained in Paragraph 91 and therefore deny the
6 same.

7 92. Paragraph 92 is directed to another defendant and thus requires no response.
8 In the alternative, Defendants are without knowledge or information sufficient to form a
9 belief as to the truth of the allegations contained in Paragraph 92 and therefore deny the
10 same.

11 93. Defendants hereby incorporate their responses to the allegations contained
12 in Paragraphs 1 through 92 as if set forth fully herein.

13 94. Paragraph 94 is directed to another defendant and thus requires no response.
14 In the alternative, Defendants are without knowledge or information sufficient to form a
15 belief as to the truth of the allegations contained in Paragraph 94 and therefore deny the
16 same.

17 95. Paragraph 95 is directed to another defendant and thus requires no response.
18 In the alternative, Defendants are without knowledge or information sufficient to form a
19 belief as to the truth of the allegations contained in Paragraph 95 and therefore deny the
20 same.

21 96. Paragraph 96 is directed to another defendant and thus requires no response.
22 In the alternative, Defendants are without knowledge or information sufficient to form a
23 belief as to the truth of the allegations contained in Paragraph 96 and therefore deny the
24 same.

25 97. Paragraph 97 is directed to another defendant and thus requires no response.
26 In the alternative, Defendants are without knowledge or information sufficient to form a
27 belief as to the truth of the allegations contained in Paragraph 97 and therefore deny the
28 same.

1 98. Defendants hereby incorporate their responses to the allegations contained
2 in Paragraphs 1 through 97 as if set forth fully herein.

3 99. Defendants admit that Omniscan™ is approved by the FDA as reasonably
4 safe for its approved uses when utilized properly, in conjunction with the medical
5 judgment of a trained healthcare professional and in accordance with its accompanying
6 warnings, instructions, and contraindications. Defendants deny the remaining allegations
7 contained in Paragraph 99.

8 100. Defendants deny the allegations contained in Paragraph 100.

9 101. Defendants deny the allegations contained in Paragraph 101.

10 102. Defendants deny the allegations contained in Paragraph 102.

11 103. Defendants deny the allegations contained in Paragraph 103.

12 104. Paragraph 104 contains a legal conclusion to which no response is required.
13 To the extent that a response is deemed to be required, Defendants deny the allegations
14 contained in Paragraph 104.

15 105. Defendants deny the allegations contained in Paragraph 105.

16 106. Defendants deny the allegations contained in Paragraph 106.

17 107. Defendants deny the allegations contained in Paragraph 107.

18 108. Defendants deny the allegations contained in Paragraph 108.

19 109. Defendants hereby incorporate their responses to the allegations contained
20 in Paragraphs 1 through 108 as if set forth fully herein.

21 110. Defendants deny the allegations contained in Paragraph 110.

22 111. Defendants deny the allegations contained in Paragraph 111.

23 112. Defendants deny the allegations contained in Paragraph 112.

24 113. Defendants hereby incorporate their responses to the allegations contained
25 in Paragraphs 1 through 112 as if set forth fully herein.

26 114. Defendants deny the allegations contained in Paragraph 114.

27 115. Defendants deny the allegations contained in Paragraph 115.

28 116. Defendants deny the allegations contained in Paragraph 116.

117. Defendants deny the allegations contained in Paragraph 117.

118. Defendants deny the allegations contained in Paragraph 118.

119. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 118 as if set forth fully herein.

120. Paragraph 120 contains a legal conclusion to which no response is required. To the extent that a response is deemed to be required, Defendants deny the allegations contained in Paragraph 120.

121. Defendants deny the allegations contained in Paragraph 121, including sub-parts (a)-(d).

122. Defendants deny the allegations contained in Paragraph 122.

123. Defendants deny the allegations contained in Paragraph 123.

124. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 123 as if set forth fully herein.

125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 125 and therefore deny the same.

126. Defendants deny the allegations contained in Paragraph 126.

Defendants deny that Plaintiffs are entitled to the relief sought in the ad damnum clause.

Defendants deny each and every statement, allegation and averment contained in the Complaint that has not been expressly admitted above.

Discovery and investigation may reveal that one or more of the following additional defenses are available to Defendants in this matter. Defendants accordingly assert the following defenses. Upon completion of discovery, if the facts warrant, Defendants may withdraw any of these defenses as may be appropriate. Defendants further reserve the right to amend this Answer to assert additional defenses and other claims as discovery proceeds. Further answering, and by way of additional defense, Defendants state as follows:

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AFFIRMATIVE DEFENSES

1
2 1. The Complaint fails to state facts sufficient to constitute a cause of action
3 and otherwise fails to state a claim upon which relief can be granted.

4 2. Plaintiffs' claims are barred in whole or in part by the doctrines of laches,
5 estoppel, waiver, unclean hands or ratification.

6 3. Defendants provided adequate warnings to Paul Jay Gerber's physicians and
7 other medical providers. Therefore, any claims by Plaintiffs for inadequate warnings are
8 barred by the learned intermediary doctrine.

9 4. Plaintiffs' claims based on inadequate warning are barred even if the
10 Defendants failed to provide adequate warnings with respect to known or potential
11 dangers or risks associated with the use of Omniscan™ because physicians and medical
12 providers prescribing Omniscan™ either knew or should have known of the potential or
13 known dangers or risks, and there is no duty to warn members of a profession against
14 dangers known or which should be known to members of the profession.

15 5. Plaintiffs' claims are barred in whole or in part because the products
16 methods, standards, and/or techniques used in manufacturing, designing, marketing,
17 and/or labeling Defendants' products complied with and/or were in conformity with the
18 state of the art at the time they were manufactured, designed, marketed, and/or labeled.

19 6. Plaintiffs' claims are barred in whole or in part because the manufacture,
20 labeling and sale of Omniscan™ was and is controlled by federal law, and the Defendants
21 at all relevant times complied with applicable statutes and with the requirements of the
22 FDA.

23 7. Plaintiffs' claims are barred in whole or in part to the extent Plaintiffs have
24 released, settled, entered into an accord and satisfaction, or otherwise compromised her
25 claims.

26 8. Plaintiffs' claims are barred in whole or in part by their assumption of the
27 risk associated with the purchase and/or use of the product.

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1 9. Plaintiffs' claims are barred in whole or in part by product misuse by
2 Plaintiff Paul Jay Gerber or his physician including, among other things, their failure to
3 follow warnings and/or failure to follow instructions.

4 10. Plaintiffs' claims under state law are barred by the doctrine of federal
5 preemption.

6 11. Plaintiffs' claims are barred in whole or in part by the deference given to the
7 primary jurisdiction of the FDA over the subject pharmaceutical product at issue under
8 applicable federal laws, rules and regulations.

9 12. If Defendants' product was unsafe (which Defendants deny), then Plaintiffs'
10 claims are barred because the product was unavoidably unsafe.

11 13. Plaintiffs' claims are barred in whole or in part under the doctrine described
12 in the Restatement (Second) of Torts § 402A cmt. k.

13 14. Plaintiffs' claims are barred in whole or in part because the pharmaceutical
14 product at issue provides net benefits for a class of patients within the meaning of
15 Restatement (Third) of Torts: Products Liability § 6 cmt. f.

16 15. To the extent Plaintiffs' claims related to Defendants' advertising,
17 marketing, public statements, lobbying or other activities protected by the First
18 Amendment to the United States Constitution and the California Constitution, such claims
19 are barred.

20 16. Plaintiffs failed to notify Defendants of any alleged breach of warranty
21 within a reasonable time after he discovered or should have discovered any such alleged
22 breach and are therefore barred from recovery on such claims.

23 17. Any warranties made by Defendants to Plaintiffs were disclaimed.

24 18. Any claim for breach of express warranty must fail because Plaintiffs failed
25 to allege any representation about the product at issue giving rise to an express warranty.

26 19. Any claim for breach of implied warranty fails because the product at issue
27 was used for its ordinary purpose.

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1 20. Plaintiffs' breach of warranty claims are barred because there is a lack of
2 privity between Plaintiffs and Defendants.

3 21. Defendants specifically plead all defenses under the Uniform Commercial
4 Code now existing or which may arise in the future.

5 22. Plaintiffs' claims of breach of warranty, express or implied, are barred by
6 the applicable provisions of the California Commercial Code.

7 23. Plaintiffs have failed to join all indispensable parties; as a result of this
8 failure, complete relief cannot be accorded to those already parties to this action and will
9 result in prejudice to Defendants.

10 24. Plaintiffs' claims and recovery are barred, reduced and/or limited pursuant
11 to applicable constitutional, statutory and common law regarding limitations of awards
12 and recovery.

13 25. Plaintiffs' claims are barred or reduced by Plaintiffs' contributory and/or
14 comparative negligence, and/or contributory and/or comparative fault.

15 26. Plaintiffs' damages, if any, were caused solely or partially by some third
16 person or third party for whom Defendants are not legally responsible.

17 27. Plaintiffs' damages, if any, resulted from new and independent,
18 unforeseeable, superseding or intervening causes unrelated to the conduct of, or product
19 manufactured, distributed or introduced into interstate commerce by Defendants.

20 28. Plaintiffs' damages, if any, were the result of pre-existing conditions
21 unrelated to any conduct of, or product manufactured, distributed or introduced into
22 interstate commerce by Defendants.

23 29. Plaintiffs' damages, if any, were caused by changes and/or alterations to the
24 Defendants' products, made by persons not within Defendants' control.

25 30. Defendants liability, if any, for non-economic loss is limited to its equitable
26 share, determined in accordance with the relative culpability of all persons or entities
27 contributing to Plaintiff's total non-economic loss, if any, including those over whom
28 Plaintiffs could have obtained personal jurisdiction with due diligence.

1 31. Plaintiffs' non-economic loss must be allocated in accordance with the
2 provision of Cal. Civil Code § 1431.1 ("Proposition 51").

3 32. Plaintiffs' damages, if any, must be reduced by any amount of damages
4 legally caused by Plaintiffs' own failure to mitigate such damages.

5 33. Plaintiffs' damages, if any, are not recoverable because they are legally too
6 remote, indirect, and speculative.

7 34. Plaintiffs' Complaint fails to state a claim upon which relief can be granted
8 for punitive or exemplary damages.

9 35. Defendants deny any conduct for which punitive or exemplary damages
10 could or should be awarded and deny that Plaintiffs have produced evidence sufficient to
11 support or sustain the imposition of punitive damages pursuant to the applicable
12 standard(s) of proof.

13 36. Plaintiffs' claims seeking punitive or exemplary damages violate the
14 substantive and procedural aspects of the Due Process Clause of the Fifth and Fourteenth
15 Amendments to the United States Constitution, the Equal Protection Clause, the Excessive
16 Fines Clause, the Commerce Clause and the cognate provisions of the California
17 Constitution.

18 37. Any award of punitive or exemplary damages is barred to the extent that it is
19 inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v.*
20 *Gore*, 517 U.S. 559, 134 L.Ed. 2d 809, 116 S.Ct. 1589 (1996), *State Farm Mutual*
21 *Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and *Phillip Morris USA v.*
22 *Williams*, 127 S.Ct. 1057 (2007).

23 38. No act or alleged omission of Defendants was vile, base, willful, malicious,
24 wanton, oppressive or fraudulent, or done with a conscious disregard for the health, safety
25 and rights of Plaintiffs and others, or with actual malice, fraud or oppression as defined in
26 Cal. Civil Code § 3294, and Plaintiffs' Complaint fails to state a claim upon which relief
27 can be granted for punitive or exemplary damages. Plaintiffs' Complaint seeks damages
28 in excess of those permitted by law. Defendants assert any statutory or judicial protection

1 from punitive or exemplary damages that is available under the applicable law, and any
2 award of punitive or exemplary damages is barred.

3 39. Any verdict or judgment that might be recovered by Plaintiffs must be
4 reduced by those amounts that have indemnified, or will in the future, with reasonable
5 certainty, indemnify Plaintiffs in whole or in part for any past or future claimed economic
6 loss from any collateral source such as insurance, social security, workers' compensation
7 or employee benefit program.

8 40. Plaintiffs' claims are barred by the applicable statute of limitations,
9 including but not limited to Cal. Code of Civil Procedure former § 340, subd. 3, or in the
10 alternative, Cal. Code of Civil Procedure §§ 335.1, 340.5, 340.8 and/or 343.

11 41. Defendants owed no duty to Plaintiffs, and in any event, violated no duty
12 that it may have owed to Plaintiffs.

13 42. Any and all injuries suffered by Plaintiffs, the fact of which is expressly
14 denied by Defendants, were the direct and proximate result of sensitivities, medical
15 conditions, reactions and/or idiosyncrasies peculiar to Plaintiff Paul Jay Gerber that were
16 unknown, unknowable or not reasonably foreseeable to Defendants, and not as a direct
17 and proximate result of wrongful conduct on the part of the Defendants, the fact of which
18 is expressly denied by the Defendants.

19 43. No act or omission of the Defendants was a substantial factor in bringing
20 about the alleged injuries of Plaintiffs, nor was any such act or omission a contributing
21 cause thereof, and any alleged acts or omissions of the Defendants were superseded by the
22 acts or omissions of others, including Plaintiffs, which were the independent, intervening
23 and proximate cause of any injury, damage or loss sustained by Plaintiffs.

24 44. Plaintiffs' cause of action for alleged violation of the California Consumer
25 Legal Remedies Act ("CLRA"), Cal. Civil Code § 1750, *et seq.*, is barred because
26 Plaintiffs failed to give proper notice as mandated by Cal. Civil Code § 1782(a)(1). Since
27 strict compliance with the notice provisions of the CLRA is required, Plaintiffs' CLRA
28 cause of action must be dismissed with prejudice.

1 45. Plaintiffs' cause of action for alleged violation of the California Consumer
2 Legal Remedies Act ("CLRA"), Cal. Civil Code § 1750, *et seq.*, is barred because
3 Plaintiffs failed to comply with the affidavit requirement of Cal. Civil Code § 1780(c).
4 Since strict compliance with the affidavit provisions of the CLRA is required, Plaintiffs'
5 CLRA cause of action must be dismissed with prejudice.

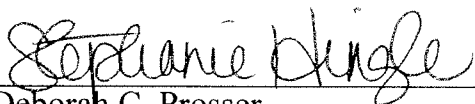
6 46. Plaintiffs' Complaint fails to state a claim under the California Consumer
7 Legal Remedies Act ("CLRA"), Cal. Civil Code § 1750, *et seq.*, because the CLRA is
8 inapplicable to a pharmaceutical products liability action.

9 47. Plaintiffs' claims are barred in whole or in part because Plaintiffs consented
10 to the alleged wrongful conduct.

11 48. Defendants adopt and incorporate by reference all defenses pled by other
12 defendants except to the extent they are inconsistent with Defendants' defenses pled in
13 this Answer.

14 Dated: November 30, 2007

KUTAK ROCK LLP

15
16 By: 
17 Deborah C. Prosser
18 Stephanie A. Hingle
19 Attorneys for Defendants
20 GENERAL ELECTRIC COMPANY
21 AND GE HEALTHCARE INC.
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PROOF OF SERVICE

Peter Jay Gerber, et al. vs. Bayer Corporation, et al.
U.S. District Court, Northern District of California,
San Francisco Division, Case No. CV-07-5918
(San Francisco Superior Court Case No.: CGC-07-468577)

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the City of Los Angeles in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is 515 S. Figueroa Street, Suite 1240, Los Angeles, California 90071.

On November 30, 2007, I served the following documents described as

**GENERAL ELECTRIC COMPANY AND GE HEALTHCARE INC.'S
ANSWER TO COMPLAINT**

on all interested parties in this action by placing a true copy or the original thereof enclosed in a sealed envelope or package addressed as stated on the attached mailing list.

[] **(BY FACSIMILE)** The facsimile machine I used complied with Rule 2.301(3) and no error was reported by the machine. Pursuant to Rule 2.306(g)(4), I caused the machine to print a record of the transmission.

[] **(BY MAIL, 1013a, 2015.5 C.C.P.)** I deposited such envelope in the mail at Irvine, California. The envelope was mailed with postage thereon fully prepaid. I am readily familiar with the firm's practice for collection and processing correspondence for mailing. Under that practice, this document will be deposited with the U.S. Postal Service on this date with postage thereon fully prepaid at Irvine, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

[XX] **(BY NOTICE OF ELECTRONIC FILING)** Counsel who have consented to electronic service have been automatically served by the Notice of Electronic Filing, which is automatically generated by CM/ECF at the time said document was filed, and which constitutes service pursuant to FRCP 5(b)(2)(D).

[] **(BY OVERNIGHT DELIVERY/COURIER)** I delivered such envelope or package to a courier or driver authorized by the express service carrier; or deposited such envelope or package to a regularly maintained drop box or facility to receive documents by the express service carrier with delivery fees provided for.

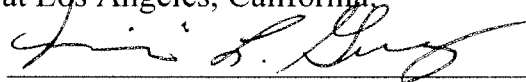
[] **(BY MESSENGER)** I served the documents by placing them in an envelope or package addressed to the persons at the addresses listed above and providing them to a messenger for personal service. (A proof of service executed by the messenger will be filed in compliance with the *Code of Civil Procedure*)

1 [] **(BY PERSONAL SERVICE)** I delivered the foregoing envelope by hand to the
2 offices of the addressee.

3 [] **(STATE)** I declare under penalty of perjury under the laws of the State of
4 California that the above is true and correct.

5 [XX] **(FEDERAL)** I declare that I am employed in the office of a member of the bar of
6 this Court at whose direction service was made.

7 Executed on November 30, 2007, at Los Angeles, California.

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Virginia L. Gomez

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